JAN 1 8 2002

K012511

510(k) Summary of Safety and Effectiveness Information

Regulatory Authority:	**Safe Medical Devices Act of 1990, 21 CFR 807.92**
Company:	**BioLase Technology, Inc. 981 Calle Amanecer San Clemente, CA 92673**
Contact:	**Ms. Ioana M. Rizoiu BioLase Technology, Inc. 981 Calle Amanecer San Clemente, CA 92673 (949) 361-1200 (949) 361-0204 Fax**
Trade Name:	***Waterlase Millennium®***
Common Name:	**Er,Cr:YSGG laser**
Classification Name:	**Surgical laser instrument**
Classification Code:	**79 GEX**

Equivalent Devices:

BioLase Technology, Inc.	***Twilite™ Millennium®***
Premier Laser Systems	***Aurora™***
Tycom Dental	***Quantec Series 2000 Files***
Tulsa Dental	***Tri Auto ZX***

Device Description:

The ***Waterlase Millennium*** dental laser system may be used to perform several dental applications. For hard tissue procedures the ***Waterlase Millennium*** utilizes the Erbium, Chromium: Yttrium, Scandium, Gallium, Garnet (Er,Cr:YSGG) laser in combination with advanced water atomization technology to cut, remove, roughen and etch tissues. Soft tissue procedures are performed using a different mode of operation where direct Er,Cr:YSGG laser energy is applied to incise, excise or ablate the tissues. In soft tissue

procedures the water spray is applied for hydration, cooling or to keep tissues clean. A flexible fiberoptic handpiece delivers the ***Waterlase Millennium*** laser energy. A visible light emitted from the handpiece distal end pinpoints the area of treatment. In both hard and soft tissue applications the power output, pulse energy, repetition rate and air and water flow rates are adjustable to specific user requirements.

Please refer to the User Manual, section 8 'Clinical Applications', for detailed instructions on how to use the ***Waterlase Millennium*** device.

Indications for Use:

Tooth preparation to obtain access to the root canal
Pulpotomy
Pulp extirpation
Pulpotomy as an adjunct to root canal therapy
Root canal debridement and cleaning
Root canal preparation including enlargement

Cautions and Contraindications:

All clinical procedures performed with ***Waterlase Millennium*** must be subjected to the same clinical judgement and care as with traditional techniques. Patient risk must always be considered and fully understood before clinical treatment. The clinician must completely understand the patient's medical history prior to treatment. Exercise caution for general medical conditions that might contraindicate a local procedure. Such conditions may include allergy to local or topical anesthetics, heart disease, lung disease, bleeding disorders, sleep apnea or an immune system deficiency. Medical clearance from patient's physician is advisable when doubt exists regarding treatment.

Substantial Equivalence:

There are no unique applications, indications, materials or specifications presented herein. For all the soft tissue indications for use, ***Waterlase Millennium*** is substantially equivalent to several erbium laser systems and diode laser systems cleared by the FDA. Equivalent devices include: BioLase, *Twilite* (K991994, for oral soft tissues including pulpotomy and pulpotomy as an adjunct to root canal therapy); Premier, *Aurora* (K981379, for pulpotomy and pulpotomy as an adjunct to root canal therapy); BioLase, *Millennium* (K980585 and K990219 for hard tissue applications); Tycom Dental, *Quantec Series 2000 Endodontic Files* (K962031 for root canal

preparation) and Tulsa Dental Products, *Tri Auto ZX* (K970339 for endodontic treatment to enlarge root canals).

Conclusion:

Waterlase Millennium is substantially equivalent to several available, established dental laser products and endodontic files driven by rotary handpieces. ***Waterlase Millennium*** performs the same indications for use through the same cutting modalities as other laser devices and endodontic files.

- Evidence of equivalence has been demonstrated through:
  - Equivalent performance specifications
  - Promotional materials for equivalent systems
  - Equivalent intended uses

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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BioLase Technology, Inc.
Iona Rizoiu
Vice President
Clinical Research and Development
981 Calle Amanecer
San Clemente, California 92673

Re: K012511
Trade Name: Waterlase Millennium®
Regulation Number: 807.92
Regulation Name: Surgical Laser Instrument
Regulatory Class: II
Product Code: MXF; GEX
Dated: November 12, 2001
Received: November 15, 2001

Dear Ms. Rizoiu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 012511

Device Name: ***WaterLase Millennium®***

Indications for Use:

Tooth preparation to obtain access to root canal
Pulpotomy
Pulp extirpation
Pulpotomy as an adjunct to root canal therapy
Root canal debridement and cleaning
Root canal preparation including enlargement

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-The-Counter-Use _____

for Mark N Milhern
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012511